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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,622	04/02/2004	Joseph R. Garlich	224297	2375

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EXAMINER	
JONES, DAMERON LEVEST	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
02/07/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/817,622	GARLICH ET AL.	
	Examiner	Art Unit	
	D. L. Jones	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7,17,18,23,27,31,37,75-77,81,82,90,92,94 and 103-127* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 7, 17, 18, 23, 27, 31, 37, 75-77, 81, 82, 90, 92, 94, and 103-127* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 1/13/08 wherein the specification was amended; claims 1, 7, 17, 18, 76, 77, 81, 82, 90, 92, 100, and 104; claims 2-6, 8-16, 19-22, 24-26, 28-30, 32-36, 38-74, 78-80, 83-89, 91, 93, 95-99, 101, and 102 were canceled; and claims 104-127 were added.

Note: Claims 1, 7, 17, 18, 23, 27, 31, 37, 75-77, 81, 82, 90, 92, 94, and 103-127 are pending.

RESPONSE TO APPLICANT'S ARGUMENTS/AMENDMENT

2. The Applicant's arguments and/or amendment filed 12/13/07 to the rejection of the claims made by the Examiner have been fully considered and deemed persuasive for reasons of record in Applicant's response. Therefore, all outstanding rejections are hereby withdrawn.

COMMENTS/NOTES

3. During the interference search, art was found that read on the instant invention. Thus, it was deemed necessary by the Examiner to make the references of record.

NEW GROUNDS OF REJECTIONS

103 Rejections

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 7, 17, 18, 23, 27, 31, 37, 75-77, 81, 82, 90, 92, 94, and 103-127 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cottam et al (US 2006/0122178) in view of Gudkov et al (US Patent No. 6,593,353).

Cottam et al disclose compounds having activity as inhibitors of apoptosis. The compounds protect mammalian cells from damaging effects of chemotherapy, irradiation, or in other situation in which it is desirable to protect tissue from the consequences of clinical and environmental stress (see entire documents, especially

abstract; pages 2-3, bridging paragraph; page 12, claims 1-9, 15-18, and 24). In particular, Applicant discloses compounds of Formula IA that overlap wit the instant invention (page 2, paragraph [0014]). In addition, Cottam et al disclose that their invention also includes a method for binding a compound of formula I (see page 2, [0009] of Cottam et al; page 7, Table 3) to cells and biomolecules comprising p53 or p53 dependent receptors, in vivo or in vitro. The biomolecules comprise ligand-bound p53 or p53 dependent receptor sites which measure the selectivity of test compounds for specific receptor subtypes or for identifying potential therapeutic agents for the treatment of diseases. The method may comprise the step of contacting the therapeutic agent with the ligand-receptor complexes and measuring the extent of displacement of the ligand and/or binding of the agent, by methods known in the art (page 3, paragraph [0018]). It should be noted that in Table 3 (page 7) disclose the survival of cells treated with various compounds encompassed by Applicant's Formula IV varies from 16-78%. The average cell survival various from 16However, Cottam et al fail to disclose that their invention is useful in reducing cell death in bone marrow cells.

Gudkov et al disclose p53 inhibitors and therapeutic use of such inhibitors (see entire document, especially, abstract; page 5, lines 10-16). Gudkov et al disclose compounds of Formula IV (column 1, lines 45-55; column 4, line 38 through column 5, line 1) that are encompassed by the instant invention. The inhibitors of Gudkov et al are directed to mediating apoptosis in tumor cells (column 2, lines 62-65). The inhibitors may be used for reducing or eliminating p53-dependent neuronal death; preserving

tissues and organs prior to transplanting; preparing a host for bone marrow; or reducing or eliminating neuronal damage during seizures.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a compound of Formula IV into a method of reducing cell death in a mammal because both Cottam et al and Gudkov et al disclose compounds of Formula IV which is useful in a method of reducing apoptosis in a mammal. In addition, it would have been obvious to one of ordinary skill in the art to use a bone targeting agent since Gudkov et al disclose that their compounds are useful in preparing a host for a bone marrow transplant. Also, the skilled artisan would recognize that the term 'biomolecule' as disclosed in Cottam et al is known in the art as encompassing a multitude of possible bone targeting agents including, for example, peptides and phosphate containing groups. In addition, the skilled artisan would recognize that Gudkov et al is not limited to any particular type of linkage of the ligand and compound of Formula IV. Thus, it would be obvious to one of ordinary skill in the at that the linkage of Cottam et al encompasses enol ether, ketal, imine, oxime, hydrazone, semi-carbazone, acylimide, and methylene radicals. Furthermore, since Cottam et al, Gudkov et al, and the instant invention all disclose compounds of Formula IV useful in reducing cell death, a skilled artisan would recognize that Cottam et al and Gudkov et al are within the same field of endeavor. Thus, the reference teachings are combinable.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

D. L. Jones
Primary Examiner
Art Unit 1618

February 2, 2008